Global Clinical Trials: Spreading the Wealth Yields Diversity

Posted: April 19, 2011

Created: 19/04/2011 - 09:22

Geoff Lomax is CIRM's Senior Officer to the Standards Working Group

In my role coordinating CIRM's Standards Working Group, I often participate in conversations about ethical implications of participating in clinical trials. In that capacity, I recently attended the annual conference for the Association for the Accreditation of Human Research Protection Professionals (AAHRPP).

These conversations are especially important given CIRM's Targeted Clinical Development Awards, which will be discussed at our next board meeting May 2-3 (information about that meeting will be available on our website 10 days before the meeting). Those awards will fund the clinical development of novel cell therapies derived from pluripotent stem cells.

The conference had a strong emphasis on international clinical research. One talk of particular interest was by Luc Truyen of Johnson & Johnson Pharmaceuticals. The talk titled, "Migration of Clinical Trails Outside of the United States: Is it a Problem?", presented data on the current international clinical trial landscape.

The punch line first, Dr. Truyen's data suggest (1) the overall volume of trial activity has grown substantially, (2) there continues to be an increase in patient enrollment and new trial sites in North America and (3) the increasing geographic diversity of trials is a measure of success.

Here are a few key points I thought were interesting:

- Cost may be a factor in limited cases. The cost of trials in the US is roughly 45% higher than China, India and Brazil â countries where increased numbers of trials are being conducted. These countries, however, also have experienced rapid growth in research and clinical capacity. Further, these countries have high incidence of diseases not common in the Untied States (e.g. hepatitis). Therefore, it is a success that they are initiating large trials to address diseases impacting their populations.
- Overseas trials are not a means of avoiding regulatory scrutiny. Major trials by manufacturers for therapeutics intended for international markets are generally conducted under a FDA Investigational New Drug (IND) application. International FDA investigator inspections have quadrupled since 2002. These trials are highly regulated.
- Trials performed overseas support scientific validity. Many overseas trial sites are chosen for scientific reasons. Reasons include (1) there is a higher concentration of disease in the area, (2) individuals have not been treated with other therapies so the effect of the trial may be measured accurately and (3) therapy development / trials have the support of the local public health / medical community.
- Globalization is creating the need for therapies suitable for a diverse world. We need international collaboration to ensure that clinical research in the U.S. and elsewhere stays applicable to the all populations.

- G.L.

Tags: aahrpp, truyen, clinical trials

Source URL: https://www.cirm.ca.gov/blog/04192011/global-clinical-trials-spreading-wealth-yields-diversity